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DDiC
Drug Delivery **innovation** Center

Drug Delivery Innovation Center DDIC @ INVITE

9 April 2018



demonstrating future production concepts

Drug Delivery Innovation Center



- The **Drug Delivery Innovation Center (DDIC)** which aims to bridge basic research and industrial applications officially started on **September 1st, 2017**.
- Founding Tier 1 members of the **open consortium** are the companies **Bayer AG, LB Bohle GmbH, Merck KGaA** (all Germany) and **UCB S.A.** (Belgium), together with the university partners **TU Dortmund** and **HHU Düsseldorf**.
- The **INVITE GmbH**, which is located in the CHEMPARK Leverkusen, Germany, **leads the consortium and builds the legal frame**.
- We are looking forward to discuss the opportunities of the DDIC with new members.



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Vision and Mission

Drug Delivery Innovation Center (DDIC)



Through partnership and close collaboration between academia, industry and public stakeholders we will build a world-class Center of Excellence in Drug Delivery Innovation. Based on established research platforms at the universities of Düsseldorf and Dortmund as well as at INVITE the DDIC will foster international, multi-disciplinary research networks.

■ Science

- Advance pharmaceutical science and innovation in close collaboration of multi-disciplinary networks with pharmaceutical industry (focus on precompetitive research)
- Increase fundamental process understanding as the base of advanced process control, modelling and prediction

■ Education

- The center supports the “master of industrial pharmacy” program at HHU Düsseldorf and offers a unique doctoral training program to develop a highly skilled talent base for industry and academia

■ Products & Innovation for Patients (better healthcare for patients)

- The center will accelerate patient-centric innovation, enabling the development of new technologies and advanced healthcare products and services

DDIC – a consortium of partners in academia and industry



A broad world-wide network of partners builds the basis for successful research as well as education and talent development to meet the needs of the pharmaceutical sector.

- **Multi-disciplinary research collaborations:**
network of universities / research institutes from different disciplines
- **International research consortia:**
e.g. with CMAC (UK), RCPE (Austria)
- **Pharmaceutical industry:**
pre-competitive basis oriented research and proprietary applications
- **Equipment Manufacturer:**
new technologies for manufacturing and testing of pharmaceuticals
- **Pharmaceutical Suppliers:**
excipient manufacturer, medical device industry (delivery technologies)

DDIC – innovative solutions for current challenges in pharmaceutical industry



Modeling and Prediction

- Rationale formulation design / pharmaceutical material science
- In-silico testing / prediction of biopharmaceutical properties
- Process modeling and simulation (DoE process optimization and scale-up)

Drug Delivery Technologies

- Oral, solid dosage form: overcoming low solubility / poor bioavailability
- Inhalation technologies (incl. medical devices)
- Ocular drug delivery (incl. medical devices)
- Advance formulations for biologics
- Drug Delivery for special patient groups (pediatrics & geriatrics)

Process Engineering

- Down-scaling (equipment & processes)
- Continuous Processing
- Advanced Process Understanding (incl. Design Space and Process-analytical technologies (PAT))

Future Technologies

- Nano-medicine, Nano-technology
- 3D-printing
- Drug delivery for cell-based / gene therapy

Research Clusters

Seven research clusters have been defined



Research Cluster

1 Low solubility / poor bioavailability of oral drugs

2 Drug delivery forms for special patient groups/ personalized medicines

3 Continuous processing

4 Fundamental process understanding/PAT/Scalability

5 Models for predicting biopharmaceutical properties

6 Drug formulations for biomolecules
(focus: mAbs and ADCs)

7 Nanomedicines / nanotechnologies

DDIC Projects

Overview on already started PhD theses



	University	Professor	Title of PhD thesis
1	TU Dortmund	G. Sadowski	Thermodynamic and kinetic stability of amorphous solid dispersions (ASDs)
2	TU Dortmund	M. Thommes	Comparison of spray drying, hot melt extrusion and single pot technology in manufacturing of ASDs
3	TU Dortmund	G. Schembecker	Disturbance prediction in continuous manufacturing of oral solid dosage forms
4	LMU Munich TU Dortmund	G. Winter C. Brandenbusch	Biopharmaceuticals: Stabilization and aggregation
5	U Düsseldorf U Greifswald	J. Breitzkreutz W. Weitschies	Customized solid drug-loaded 3D-printed implants
6	U Düsseldorf	P. Kleinebudde	Evaluation of PAT tools for defining control strategies
7	U Düsseldorf	P. Kleinebudde	Regime maps for twin-screw granulation (TSG)
8	U Düsseldorf	J. Breitzkreutz	Printed flexible drug-loaded instillations: Manufacturing and biopharmaceutical performance

Current Academic Partners



HHU Düsseldorf:

Prof. Dr. J. Breitzkreutz

Prof. Dr. Dr. h.c. P. Kleinebudde

TU Dortmund:

Prof. Dr. G. Schembecker

Prof. Dr. G. Sadowski

Prof. Dr. M. Thommes

Univ. Greifswald:

Prof. Dr. W. Weitschies

LMU Munich:

Prof. Dr. G. Winter

DDIC Partner Concept

Two options to become a partner within the DDIC consortium



Tier 1

200 T€ p.a., fix for 5 years

- Member of Scientific Board (SB)
Definition of research topics at DDIC
- Full access to Technical Committees (TC)
PhD program review
- PhD mentoring
Individual PhD
- Free technical licenses to IP
- Further.
All rights granted to Tier 2 partners

Tier 2

25 T€ p.a., fix for 3 years*

- SB: One representative of all Tier 2 partners
- For projects with material contributions
 - *PhD program review in TCs*
 - *Royalty-bearing licenses*
- Detailed access to only one PhD work in TC
- Access to
 - *DDIC facilities*
 - *Talent pool*
 - *Public funding consortia*
 - *Publications*
- Scientific community network
 - *Preferred partner for community*
 - *Technology trends*

**In-kind contributions possible*

The DDIC provides a range of benefits to its members



- Access to the Open-Innovation Platform at INVITE
- Unique network of partners along the pharmaceutical value chain
- Shape technology development in the area of drug delivery with partners in academia and industry in a pre-competitive environment
- INVITE offers the capabilities and experience (e.g. f3-factory) to set-up and successfully run publicly funded projects. Partners of DDIC will have the opportunity to join the (international) consortia for these projects
- First-hand insights into all joint research projects (20-30 PhD and master programs in steady state envisioned together with partner universities), thus substantially increasing return on own research investment via technical committee.
- Option to run proprietary research projects as part of on-going PhD-studies or as separate PhD-studies
- Temporary staff exchange (to DDIC or from DDIC to company) for training and development of new capabilities.
- Access to talents (i.e. graduates of PhD and master programs)
- Free technical non-exclusive, world-wide license to IP developed at the DDIC

Executive Summary



- The Drug Delivery Innovation Center (DDIC) builds on strong academic research and many industrial companies in the pharmaceutical sector and will expand to create an international, multi-disciplinary network in the area of Drug Delivery Innovation.
- The center aims to bridge basic research and industrial applications, strengthen pharmaceutical education (master of industrial pharmacy and PhD-programs) and ultimately deliver patient-centric innovation for better healthcare.
- The location – directly connected to INVITE and the CHEMPARK Leverkusen - provides the optimal infrastructure for research and can be easily reached by private and public transportation.
- The DDIC offers privileged memberships to a broad range of players in the pharmaceutical industry along the value chain.

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